

April 12, 2000

Mr. Lewis D. Andrews, Jr.
Glass Packaging Institute
1627 K Street, N.W.
Suite 800
Washington, D.C. 20006

RE: FAP 5B4450 and FAP 5B4451

Dear Mr. Andrews:

This is in response to your December 11, 1998, letter commenting on the potential environmental impact of FDA's approval of the two food additive petitions cited above, Docket numbers 95F-0130 and 95F-0129. These petitions, submitted by Shell Chemicals Company, requested FDA approval of naphthalate-containing polyesters.

As you know, the Food and Drug Administration Modernization Act of 1997 established a premarket notification process as the primary method for authorizing a new use of a food additive that is a food contact substance. In a letter dated October 26, 1999, the agency told petitioners who had pending food additive petitions involving the use of a food contact substance, that the petition might be eligible for premarket notification under section 409(h) of the Federal Food, Drug, and Cosmetic Act. The sponsors were told that they could consider withdrawing the petition and resubmitting it as a notification. Subsequently, Shell Chemicals Company submitted notifications for the uses requested in food additive petitions 5B4450 and 5B4451 and these notifications became effective on March 23, 2000. See the agency's internet site at <http://www.cfsan.fda.gov> under FCN numbers 000008 and 000009.

We considered in depth your comments as part of our environmental review and are now providing, for you information, our response to those comments. In your letter you said that Shell had underestimated the potential market for articles made with the subject copolymers and that the introduction of the subject copolymers as food-packaging materials could adversely affect the current recycling of various materials from municipal solid waste. You also suggested that FDA consult with the Environmental Protection Agency's Office of Solid Waste on the potential environmental impact of these petitions. We note that, although you do not specify the date of the environmental assessments (EAs) on which you base your December 11, 1998, letter, it appears that you have based the letter on the December 20, 1994, EA submitted for FAP 5B4450 and the December 28, 1994, EA submitted for

95F-0129

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FAP 5B4451. Shell submitted updated EAs to the agency and we placed them at the Docket as soon as was possible. The updated EAs for FAP 5B4450 are dated November 4, 1998, May 10, 1999, and August 4, 1999 and the updated EA for FAP 5B4451 is dated August 26, 1999. These EAs contain information about substantially larger market volumes and additional studies related to recycling articles made with the subject copolymers in the current recycling stream. We have reviewed this additional information and believe that the most recently updated EAs adequately address the two concerns you expressed: underestimating the market and adverse effects on recycling. Furthermore, we have evaluated the environmental information submitted by Shell and others and have found that allowing these notifications to become effective will not have a significant effect on the human environment. Therefore, we believe that it is not necessary to consult the Environmental Protection Agency. The documents the agency prepared as part of its environmental review for these notifications, the Findings of No Significant Impact (FONSI) and the supplement to the EAs, are enclosed. The EAs submitted by Shell Chemicals Company are displayed at the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, under Docket Number 95F-0130 (for FAP 5B4450) and Docket Number 95F-0129 (for FAP 5B4451).

Thank you for conveying your concerns to us. We hope that the updated EAs and the enclosed documents will enable you to understand the basis for our findings on these actions.

Sincerely,

Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition

3 Enclosures:
FONSI for FCN No. 000008
FONSI for FCN No. 000009
Supplement to the EAs